

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

United States Patent [19]
Giannestras et al.

[11] 3,872,519
[45] Mar. 25, 1975

[54] TOTAL ANKLE PROSTHESIS

[76] Inventors: Nicholas J. Giannestras, 1707 E. McMillan, Cincinnati, Ohio 45206; Giacomo J. Sammarco, 5811 Marlborough Dr., Cincinnati, Ohio 45230

[22] Filed: Apr. 4, 1974

[21] Appl. No.: 457,804

[52] U.S. Cl. 3/1, 128/92 C
[51] Int. Cl. A61f 1/24
[58] Field of Search.... 3/1; 128/92 C, 92 CA, 92 R

[56] References Cited

UNITED STATES PATENTS

3,521,302 7/1970 Muller 3/1

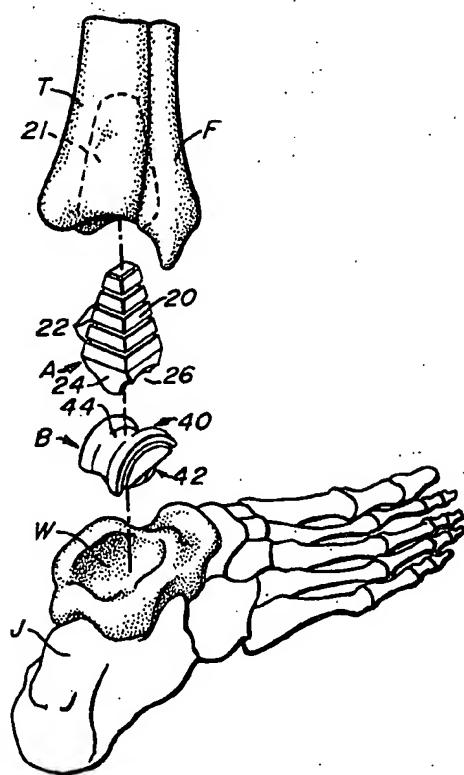
3,715,763 2/1973 Link 3/1
3,728,742 4/1973 Averill et al. 3/1
3,748,662 7/1973 Helfet 3/1
3,806,961 4/1974 Muller 3/1

Primary Examiner—Ronald L. Frinks

[57] ABSTRACT

The total ankle prosthesis comprises a tibial member and a talar member each having complementary bearing surfaces which are constructed and arranged in such a manner that the normal axial rotation of an ankle about the axis of a tibia during motion of the talus relative to the tibia during flexion and extension is reproduced by the prosthesis.

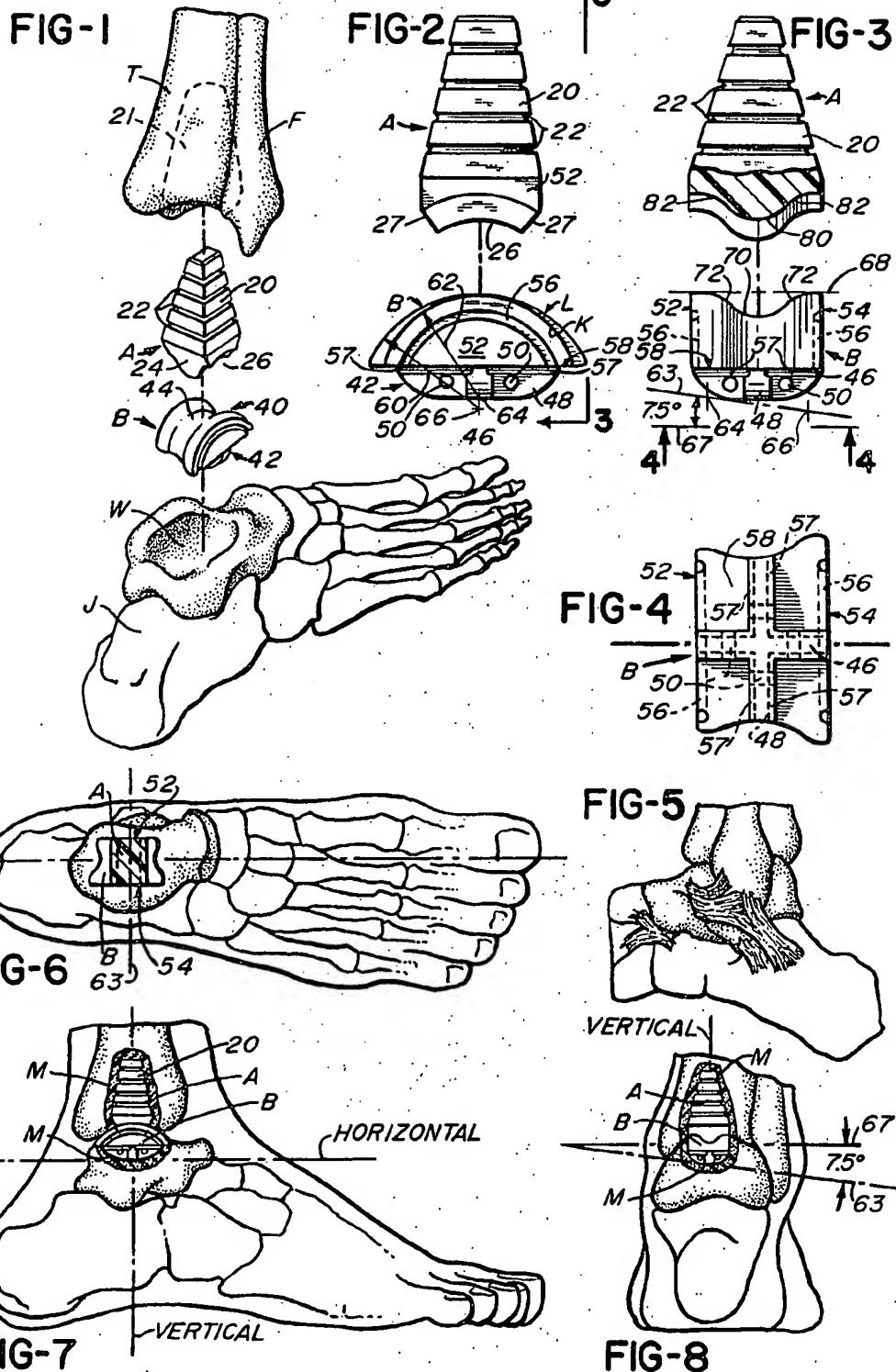
9 Claims, 15 Drawing Figures



PATENTED MAR 25 1975

3,872,519

SHEET 1 OF 2



PATENTED MAR 25 1975

3,872,519

SHEET 2 OF 2

FIG-9

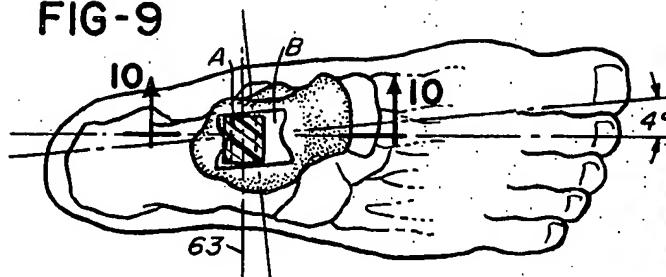


FIG-10

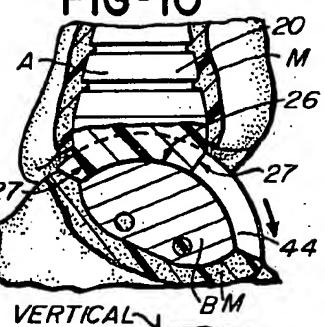


FIG-11

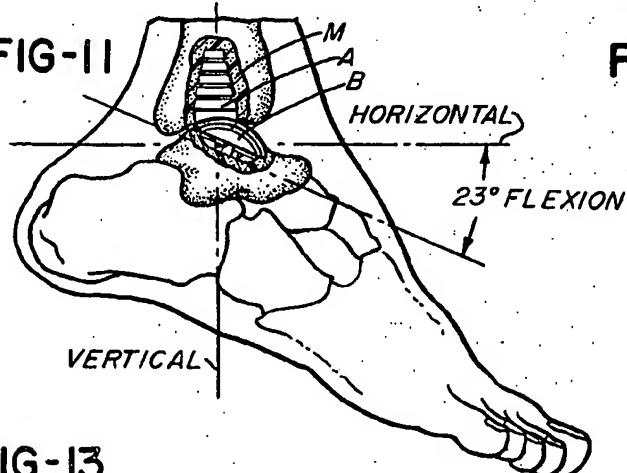


FIG-12

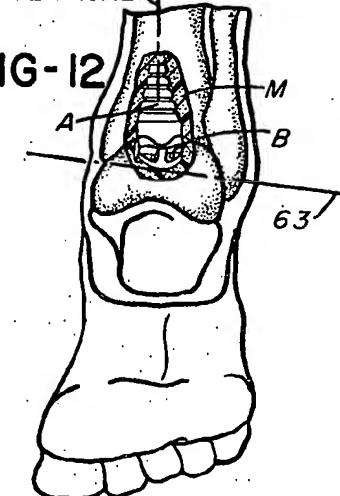
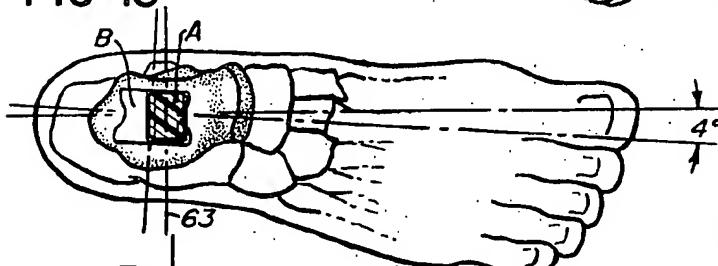


FIG-13



VERTICAL

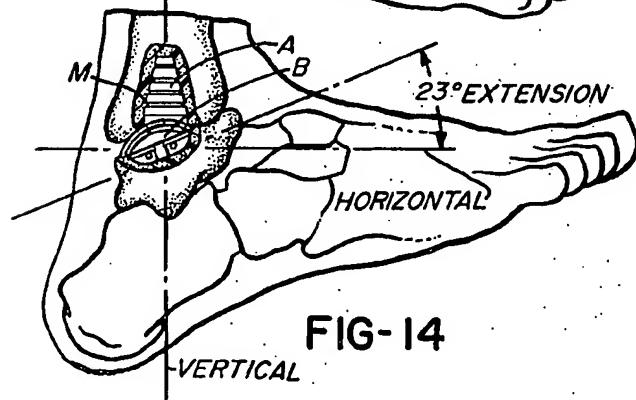


FIG-14

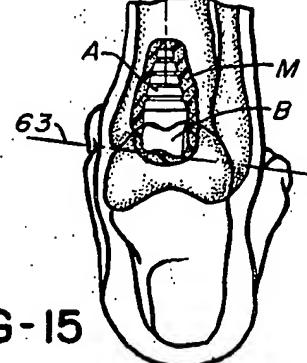


FIG-15

1
TOTAL ANKLE PROSTHESIS**BACKGROUND OF THE INVENTION****1. Field of the Invention**

The interrelationship of the mating surfaces of the tibia and talar portion of the foot in a normal ankle are such that the foot is subjected to medial rotation incident to flexion of the foot, and to lateral rotation incident to extension thereof. Heretofore when prostheses have been substituted for the damaged or diseased portions of the bearing surfaces of the tibia and talus, the resultant ankle action has not permitted the concurrent and automatic medial and/or lateral rotation of the foot incident to movement from positions of flexion to positions of extension.

The subject invention relates to a total ankle joint prosthesis which comprises tibial and talar members, each of which are provided with complementary bearing surfaces which are so constructed and arranged that the movements of an ankle provided with the subject prosthesis will closely simulate the movements of a normal ankle between positions of flexion and extension.

2. Description of the Prior Art

Applicants are familiar with the prosthesis as disclosed in each of the following U.S. Patents:

3,715,763	3,506,982	3,521,302	3,466,669
3,728,742	3,638,243	3,651,521	3,528,109
3,748,662	3,688,316	3,708,805	3,656,186
3,140,712	3,178,728	3,744,061	3,745,590

U.S. Pat. No. 3,715,763 discloses a knee prosthesis, as best illustrated in FIGS. 1 and 2 of that patent, comprising a curved steel implant 7 having polished outside surface which is adapted to rockingly engage the upper surface of a second implant fabricated from high polymer polyethylene. Implant 7 includes a pair of outwardly projecting anchoring members 14 which are received within anchoring holes milled into the natural bones where they are retained in place with acrylic resin bone cement. Implant 8 is provided with an anchoring bar 18 which is received within anchoring holes milled or otherwise provided in the upper end of the shin bone to which it is permanently affixed by the aforesaid cement.

U.S. Pat. No. 3,748,662 discloses a replacement for the bicondylar joints in human limbs wherein the prosthesis comprises two pairs of co-acting male and female load-bearing condylar components 16 and 17 each of which include integrally formed pegs 20 and 21, respectively, which are receivable in holes drilled into the bones to which they are secured by a low friction synthetic resin, plastic material.

U.S. Pat. No. 3,728,742 discloses a knee or elbow prosthesis which includes an upper member comprising a pair of laterally spaced, interconnected, intercondyloidal member each of which have a spherically curved downwardly facing convex surface which engages a spherically curved upwardly facing concave surface of each of a pair of laterally spaced interconnected lower members for providing articulation of the bones to which said members are secured in a single plane.

The prosthesis disclosed in each of the three aforesaid patents permits a rocking and/or sliding movement between the adjacent-contacting, mating surfaces of the implant members.

SUMMARY OF THE INVENTION

The present invention relates to a total ankle prosthesis which comprises a tibial member, preferably fabricated from biologically compatible high density polyethylene, or the like, wherein said member includes an elongate attachment or anchoring portion which is adapted to be received within and permanently affixed within a socket provided in the lower ends of the tibia and fibula, said tibial member having a contoured lower bearing surface which is adapted to continuously and at all times make complete contact throughout its bearing surface with the complementary bearing surface of a talar member, fabricated from a biologically compatible metal. The talar member includes a lower anchoring portion which is adapted to be permanently affixed to a socket provided in the talar dome. The bearing surface of the talar member is considerably longer than the length of the bearing surface of the tibial member whereby to permit the talar member to be moved relative to the tibial member for providing movement of the foot from 23° flexion to 23° extension and wherein the foot will be subjected to lateral rotation as it is moved to a position of extension and wherein the foot will be subjected to medial rotation as the foot is moved to a position of flexion.

The structural details of the two elements which collectively constitute the prosthesis have been designed in such a manner as to require a minimal amount of bone removal for securing the members to the tibia and talar portions of the ankle and wherein the function of the normal ligaments of the ankle are preserved.

BRIEF DESCRIPTION OF THE DRAWINGS

35 FIG. 1 is an exploded, perspective view illustrating the relationship of the subject prosthesis relative to the lower end of the tibia and fibula and the upper portion of the talus.

40 FIG. 2 is an enlarged view of the medial side of the tibial and talar members of the subject prosthesis.

45 FIG. 3 is an anterior view of the prosthesis of FIG. 2 taken along line 3—3 and with a portion of the tibial member in section for clarity of detail and understanding.

50 FIG. 4 is a bottom elevational view of the lower surface of the talar member as viewed from 4—4 of FIG. 3.

55 FIG. 5 is a partial, schematic representation of the lateral aspect of an ankle illustrating certain of the ligaments thereof.

FIG. 6 is a top view of a foot showing the relationship of the tibial and talar members of the prosthesis when the foot is in a neutral position as when resting flat on a horizontal support surface.

FIG. 7 is a lateral view, partly in section, of the foot and ankle of FIG. 6.

FIG. 8 is a view, partly in section, from the back of the heel as seen from the left side of the foot of FIG. 6.

60 FIG. 9 is a view similar to FIG. 6 showing the relationship of the tibial and talar members of the prosthesis when the ankle has been moved from the position of FIG. 6 to a position of flexion or plantarflexion.

65 FIG. 10 is a view taken on line 10—10 of FIG. 9.

FIG. 11 is a lateral view of the foot and ankle of FIG. 9.

FIG. 12 is a view, partly in section, from the back of the heel as seen from the left side of FIG. 11.

FIG. 13 is a view similar to FIG. 6 showing the relationship of the tibial and talar members of the prosthesis when the ankle has been moved from the position of FIG. 6 to a position of extension or dorsiflexion.

FIG. 14 is a lateral view of the foot and ankle of FIG. 13.

FIG. 15 is a view, partly in section, from the back of the heel as seen from the left side of FIG. 14.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

With particular reference now to FIGS. 1, 2, and 3, the letter A designates, generally, the tibial prosthesis member and the letter B designates the talar prosthesis member each of which embody the teachings of the present invention. The letters T and F, respectively, indicate the lower ankle-adjacent ends of the tibia and fibula bones, whereas the letter J denotes the heel or calcaneus bone and the letter W indicates the talar dome with a portion removed to accommodate the talar member of the prosthesis.

The tibia member may be fabricated from biologically compatible high density polyethylene or high or ultra-high molecular weight polyethylene and includes an upper, tapered, pyramidal shaped attachment portion 20 having a plurality of laterally spaced, circumferentially extending grooves 22 in the outer surface thereof. The lower portion 24 terminates in a lower bearing surface 26.

The talar member B may be fabricated from a biologically compatible metal alloy consisting of cobalt, chromium, and molybdenum, and includes an upper portion 40, a lower attachment portion 42, wherein the upper portion is provided with a bearing surface 44 which is complementary to bearing surface 26 of the tibial member A.

As best illustrated in FIGS. 2, 3, and 4, the lower portion 42 of the talar member is provided with a transverse rib 46 and a longitudinal rib 48 each of which are, in the preferred form of the invention, provided with passageways 50, as illustrated. A groove 57 is also preferably provided on each side of the base of each of ribs 46 and 48 of the talar member of the prosthesis. The medial and lateral faces 52 and 54, respectively, of the talar member are preferably provided with arcuate grooves 56. The lower surface 58 of the upper portion of the talar member is substantially flat.

With particular reference now to FIGS. 2 and 3, it will be noted that the arcuate shape of surface K on the medial side 52 of the talar member is defined by radius 62, whereas the arcuate shape of surface L on the lateral side 54 is defined by radius 60, it being noted that radius 60 is greater than radius 62. As illustrated in FIGS. 2 and 3, the centers from which radii 60 and 62 are swung are indicated at 64 and 66, respectively, said centers being located on an axis 63, which is inclined 7.5° from a horizontal reference plane 67, see FIG. 3.

As illustrated in FIG. 3, reference line 68, which is tangential with the uppermost surface of the talar member as defined by radii 60 and 62, is parallel with bottom surface 58 of the talar member and in parallelism with reference plane 67.

It will be noted that the length of the bearing surface of the talar member when viewed from its medial side, as seen in FIG. 2, is generally convex and as illustrated

in FIG. 3 it is characterized by a central, arcuate channel 70, which is flanked, on its opposite sides, by upwardly and outwardly extending wing portions 72.

The bearing surface of the tibial member, when viewed from its medial side, as in FIG. 2, is generally concave and, as illustrated in FIG. 3, is characterized by an elongate, central, depending rib 80 which is flanked, on opposite sides, by upwardly and outwardly extending wing portions 82.

10 The aforesaid bearing surfaces of the talar and tibial members are complementary to one another whereby the entire bearing surface 26 of the tibial member makes a 100% overall contact with the bearing surface 44 of the talar member throughout all positions of relative movement of the talar member with respect to the tibial member.

15 The bearing surface of the talar member as defined by the central, arcuate channel 70 and wing portion 72 may be referred to as a single groove, double-ridged, surface, whereas the central depending rib 80 and wing portions 82 of the tibial member may be referred to as a single-ridge, double grooved surface.

20 The complementary deep arcuate channel or single groove 70 at the center of the talar member of the prosthesis maintains stability while the patient is standing whereas the total contact characteristics of the bearing surfaces allow for long and even wear.

25 From the foregoing, it will be noted that the two contacting surface areas are slightly conical in shape, 30 wherein the axis of the cone is 7.50° down from the surface of the cone, as best illustrated in FIG. 3.

35 The resultant action of the bearing surface of the talar member as it slides upon the bearing surface of the tibial member produces flexion and extension in the sagittal plane and internal and external rotation in the transverse plane. This unique feature of the subject prosthesis closely simulates the physiologic motion in a normal ankle.

40 The pyramidal attachment portion 20 of the tibial member is adapted to be inserted into socket 21 provided in and in open communication with the lower end of the tibia T wherein the tibial prosthesis will be permanently secured to the bone by means of a biologically compatible cement M, such as methylmethacrylate or the like, as noted, by way of example, in FIG. 7.

45 A suitable socket is provided in the talar dome W, dimensioned to receive the lower portion 42 of the talar member, the fins 46 and 48 of which are adapted to be embedded within methylmethacrylate which will also fill passageways 50 and various grooves 56. The talar member is designed to sacrifice a minimal amount of joint surface by retaining most of the capsule and ligaments around the ankle for support.

50 55 The tibial member is made of plastic, such that cold flow of the plastic can be effectively constrained within limits of the tibia.

55 The ribs and grooves of the talar member are unique in the sense that they prevent the prosthesis from being forced out of the methylmethacrylate at the limits of motion or loosening from severe torque about the ankle. With particular reference to FIG. 2, it will be noted that the front and rear edges of the bearing surface of the tibial member, which defined the anterior and posterior limits of the sliding surface of the tibial member, are chamfered as at 27 on its articular riding surface whereby to prevent chipping of the adhesive cement at

the limits of motion between the prosthetic members, thus effectively preventing loosening of the talar member.

FIG. 5 is a schematic representation of the lateral aspect of an ankle with the ligaments illustrated. These ligaments are preserved, if they are present at the time the prosthesis is inserted. Likewise, the ligaments which hold the medial aspect of the ankle together are preserved when the prosthesis is inserted.

In FIGS. 6, 7 and 8, the supporting surface of the tibial member is in 100% overall contact with the central portion of the supporting surface of the talar member for thereby illustrating the relationship of the tibial and talar members with the foot in a neutral position or with the patient standing with his foot flat on the floor. It will be noted from FIGS. 4, 6, 9 and 13 that the medial side of the prosthesis is not quite as long as the lateral side, because the prosthesis is shaped like a truncated cone with the apex medial.

As clearly illustrated in FIG. 7, the attachment portion 20 of the tibial member extends into the tibia for at least 1 1/4 inch whereas the attachment portion of the talar member does not extend into the talar dome more than 5/8 inch.

In FIG. 8, the axis of the truncated talar cone is shown as 7.50° from the surfaces of the prosthesis at the ankle joint, and this relationship constitutes a unique and novel feature of the subject ankle joint.

FIG. 9 illustrates the manner in which the talar member of the prosthesis is simultaneously tilted forwardly and rotated inward about the tibial member for providing, as illustrated in FIG. 11, 23° flexion or plantarflexion and 4° of adduction, that is, movement of the foot toward the mid-line of the body. FIG. 12 illustrates the manner in which axis 63 of the cone of the talar prosthesis is tilted 7.50° below the horizontal from medial to lateral when the foot is disposed in a position of flexion when inclined 23° from horizontal as in FIG. 11.

When the ankle is moved from a position of 23° flexion through its central neutral position to a position of 23° extension as in FIG. 14, with the foot inclined upwardly 23° relative to a horizontal plane approximately 4° abduction is produced in the ankle joint, that is, movement of the foot away from the mid-line of the body. When the ankle is in a position of extension the forward portion of the supporting surface of the talar member will engage the lower surface of the tibial member.

With reference to each of FIGS. 6-15, it should be understood that the tibial member A is fixed or stationary at all times by reason of its permanent attachment to the lower end of the tibia. The talar member and the foot move relative to the lower bearing surface of the tibial member.

From the foregoing, it will be noted that both extension (dorsiflexion) and flexion (plantarflexion) movements are maintained with physiologic limits which were determined through radiographic studies on living humans. The subject prosthesis permits approximately 23° of extension and a like amount of flexion accompanied by axial rotation of the ankle relative to the axis of the tibia approximating 8°. The tibial and talar members of the prosthesis replace the tibial and talar surfaces, respectively, in the horizontal plane in such a manner that the medial and lateral malleoli of the ankle will not be sacrificed for the prosthesis.

The bearing surfaces of the tibial and talar members are adapted for substantially friction free relative sliding motion, and once the prosthesis has been implanted the bearing surfaces will be lubricated by patient's own synovial fluid.

What is claimed is:

1. An ankle prosthesis comprising a tibial member and a talar member, wherein the talar member includes an upper bearing surface characterized by a central, elongate, arcuate channel having upstanding wing portions on opposite sides thereof, and wherein the tibial member includes a complementary, lower bearing surface characterized by a central depending rib having wing portions on opposite sides thereof, the bearing surface of said talar member being shaped so as to impart limited lateral rotation thereto as it is moved from a central, neutral position to a position of extension with respect to the tibial member, and to impart limited medial rotation thereto as it is moved from a central, neutral position to a position of flexion with respect to said tibial member; said tibial and talar members each including means for attachment to bone structures and providing for substantial articulation thereof.
2. An ankle prosthesis as called for in claim 1, wherein the arcuate channel and wing portions of the bearing surface of the talar member make full and overall contact with the rib and wing portions, respectively, of the bearing surface of the tibial member throughout all positions of the talar member with the tibial member.
3. An ankle prosthesis as called for in claim 1, wherein the overall width of the bearing surface of the tibial member, between its medial and lateral sides, is substantially equal to the overall width of the bearing surface of the talar member between its medial and lateral sides.
4. An ankle prosthesis as called for in claim 3, wherein the overall length of the bearing surface of the talar member exceeds the overall length of the bearing surface of the tibial member whereby to provide flexion and extension movement of the talar member relative to the tibial member while maintaining full contact between the bearing surface of the tibial member with the bearing surface of the talar member.
5. An ankle prosthesis as called for in claim 1, wherein the tibial member is fabricated from a plastic, and wherein the talar member is fabricated from metal.
6. An ankle prosthesis as called for in claim 1, wherein the medial and lateral portions of the bearing surface of the talar member are defined by a cone, the sides of which taper 1 1/2°.
7. A prosthesis as called for in claim 1, wherein the shape and contour of the bearing surface of the talar member is such as to impart about 4° medial rotation of said member as it is moved from a central, neutral position to a position of about 23° flexion with respect to the bearing surface of the tibial member.
8. An ankle prosthesis as called for in claim 1, wherein the shape and contour of the bearing surface of the talar member is such as to impart about 4° lateral rotation to said member as it is moved from a central, neutral position to a position of about 23° extension with respect to the bearing surface of the tibial member.
9. An ankle prosthesis as called for in claim 4, wherein the front and rear edges of the bearing surface of the tibial member define the bases of upwardly and outwardly inclined anterior and posterior faces of said member.

* * * * *